Leaders in Bioequivalence and Bioavailability Studies

Celerion is a leader in clinical pharmacology studies such as drug-drug-interaction, bioavailability and bioequivalence studies. Our breadth of experience, expertise and efficient solutions, coupled with purpose-built facilities, including co-located pharmacy and clinical laboratories ensures your study is completed with the highest quality and on time.

Bioequivalence (BE) is the absence of a statistically significant difference in exposure to a drug product. Pharmacokinetic (PK) BE studies compare a Test vs. Reference or Comparator drug product or formulation. A BE PK study may be conducted to compare a change in drug formulation, such as capsule to tablet, change in route of administration, drug production transfer to a new manufacturing site, or as part of an Abbreviated New Drug Application (ANDA). Two (or more) drug products containing the same drug substance(s) with the same drug dose levels are considered bioequivalent if their relative bioavailability, the rate and extent of drug absorption, are within acceptable and predefined limits.

Bioavailability (BA) is the proportion of a drug that enters into circulation. Absolute BA is calculated by determining exposure of a drug when administered orally compared to intravenous (IV) administration. The absolute BA assessment can be combined with an ADME study utilizing a microtracer IV dose. If no IV data are available, relative BA is assessed by comparing drug exposure following administration of two extravascular doses. The impact of food or concomitantly administered drugs on BA of a particular drug is examined in Food Effect or Drug-Drug Interaction studies, respectively.

Celerion Differentiators for BE/BA Studies:

Experience:

- Conducted over 450 bioequivalence/bioavailability studies since 2010
- Experience with multiple comparator product studies and statistical analysis

Expertise:

- Highly-qualified, integrated team of biostatisticians, PK scientists, medical writers and subject matter experts provide input into study design, analysis and reporting.
- Celerion is a member of the Clinical Data Interchange Standards Consortium (CDISC) and supports the submission of compliant SDTM and ADaM packages for regulatory submissions across multiple therapeutic areas.
- Regulatory support ensures high-quality regulatory documentation and timely communication with regulatory agencies such as the FDA.

Efficiencies:

- Over 650 beds with proven ability to run large programs of studies simultaneously.
- Multiple clinical research sites, covering US and European geographies, and dedicated recruitment team to ensure studies are started and complete on time.
- Data flow within our systems (clinical, bioanalysis and PK/biostatistics) is automated and error proof, thereby streamlining efficiency and minimizing risk.
- Real-time data access via Celexus™ to make data-driven decisions faster.
- Library of BE/BA study designs to optimize custom-made study design and protocol.

Study Design Characteristic	Bioequivalence Study	Bioavailability Study
Study Purpose	Evaluate (non-)equivalence of drug exposure for different drug products or formulations	Compare drug exposure following different routes of administration, under different conditions or for distinct formulations
Study Type	• Pilot or Pivotal BE • Endogenous compounds (ex. dopamine, epinephrine) • Comparable adhesion BE (ex. transdermal patches)	• Absolute or relative BA • Microtracer BA • Food Effect (high-fat and/or low-fat meal)
Drug Formulation	Solutions, capsules, tablets, granules, powders for suspensions, chewable, sprinkles, sublingual, transdermal, aerosols, and others	Often solutions, capsules or tablets
Route of Administration	Any route of administration	Extravascular route and IV (absolute BA) or 2 extravascular routes (relative BA)
Participants	Healthy volunteers, males and females	
Sample size	*For pivotal study:* Sample size calculation needed to achieve a pre-specified power and pre-specified type 1 error *For pilot study:* ~12-16 participants	
Key PK Parameters	AUC, C_{max}	AUC, C_{max}, F
Statistical Analysis	90% confidence interval for the geometric mean ratio of PK parameters should lie within a range of 80 - 125% to establish BE	

AUC, area-under-the curve; **C_{max}**, maximal concentration; **F**, absolute bioavailability.